UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 22-cv-10697

TRACY HUNT

v.

COVIDIEN LP, COVIDIEN SALES LLC,
COVIDIEN HOLDING INC., and MEDTRONIC, INC.

MEMORANDUM AND ORDER ON
COVIDIEN'S MOTION TO DISMISS
FOR FAILURE TO STATE A CLAIM

August 18, 2022

STEARNS, D.J.

On May 9, 2019, during a procedure to repair Tracy Hunt's laparoscopic hiatal hernia, surgeons used a surgical stapler handle and stapler reloads manufactured by Covidien to create a gastric sleeve. Some two weeks later, Hunt presented to the emergency room with symptoms of sepsis. A further examination revealed that an abscess had formed at the staple line site where the stomach meets the esophagus. Hunt underwent a successful second procedure to drain the abscess and thereafter received additional antibiotic and therapeutic treatment until her discharge on June 3, 2019.

Hunt eventually brought this lawsuit against Covidien LP, Covidien Sales LLC, Covidien Holdings Inc., and Medtronic, Inc. (together, Covidien), alleging breach of warranty, negligence, negligent misrepresentation, and violation of Mass. Gen. Laws ch. 93A. Covidien now moves to dismiss Hunt's claims. For the reasons stated below, the court will allow in part and deny in part Covidien's motion.

DISCUSSION

"The sole inquiry under Rule 12(b)(6) is whether, construing the well-pleaded facts of the complaint in the light most favorable to the plaintiffs, the complaint states a claim for which relief can be granted." *Ocasio-Hernandez v. Fortuno-Burset*, 640 F.3d 1, 7 (1st Cir. 2011). In most circumstances, the plaintiff need not demonstrate a "heightened fact pleading of specifics," but rather must present "only enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Accordingly, facts that are "merely consistent with" a defendant's liability are inadequate. *Id.* Further, the

recitation of the elements of a claim, "supported by mere conclusory statements," is insufficient to establish facial plausibility. *Id.*

Counts I and II – Breach of Warranty

Pursuant to "the Uniform Commercial Code, . . . a warranty that goods . . . are merchantable is implied in a contract for their sale, and goods are merchantable if they are 'fit for the ordinary purposes for which such goods are used.'" *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 422 (2013), quoting *Haglund v. Philip Morris, Inc.*, 446 Mass. 741, 746 (2006). "A seller breaches its warranty obligation when a product that is 'defective and unreasonably dangerous' . . . for the '[o]rdinary purposes' for which it is 'fit' causes injury." *Haglund*, 446 Mass. at 746, quoting *Colter v. Barber-Greene Co.*, 403 Mass. 50, 62 (1988). "A plaintiff in a product liability case must demonstrate '(1) the defendant produced or sold a defective product and (2) the product caused the plaintiff's injury.'" *Burnham v. Wyeth Labs., Inc.*, 348 F. Supp. 3d 109, 111-112 (D. Mass. 2018), quoting *Fertik v. William Stevenson, M.D.*, 186 F. Supp. 3d 98, 101-102 (D. Mass. 2016). "A product may be defective and unreasonably dangerous because of a manufacturing defect, a design defect, or a warning defect, that is, a failure reasonably to warn of the product's foreseeable risks of harm." *Evans*, 465

Mass. at 422. As Hunt has pleaded all three types of potential defect, the court will discuss each alleged defect in turn.

Manufacturing Defect (Count I)

Under Massachusetts law, a manufacturing defect occurs where "a particular product[,] rather than a line of products, is alleged to be defective because of negligence in the manufacturing process." *Smith v. Ariens Co.*, 375 Mass. 620, 626 (1978). Thus, "to establish a manufacturing defect, a plaintiff must demonstrate that there is a 'deviation from the design [that] rendered the product unreasonably dangerous and therefore unfit for its ordinary purposes.'" *Burnham v. Wyeth Labs., Inc.*, 348 F. Supp. 3d 109, 112 (D. Mass. 2018), quoting *Back v. Wickes Corp.*, 375 Mass. 633, 641 (1978).

Here, the court concludes that Hunt has plausibly pleaded that the manufacture of the stapler handle was defective and thus caused her injury. Hunt alleges that the EGIAUXL stapler handle used in the procedure deviated from its original design by not creating an adequate anastomosis – put differently, the stapler handle failed to properly seal off the remaining section of Hunt's stomach. *See* First Am. Compl. (FAC) (Dkt # 4) ¶¶ 48-52. This alleged failure, taken as true for purposes of the motion to dismiss, plainly caused Hunt injury, as she developed an abscess by the staple line

site that required corrective surgery and additional treatment. *Id.* ¶¶ 50-54. The fact that the EGIAUXL stapler handle was under active recall at the time the surgery took place[1] provides additional momentum for the pushing of Hunt's claim over the dividing line that separates an allegation that is "merely consistent" with a manufacturing defect from one that is legally plausible. *Iqbal*, 556 U.S. at 678.

Design Defect (Count I)

Manufacturers have "the duty to design [their] product[s] so that [they are] reasonably fit for the purpose for which [they were] made." *Ariens Co.*, 375 Mass. at 623. "For a product to be defective, it must be 'made according to an unreasonably dangerous design' and does not meet a consumer's reasonable expectation as to its safety.'" *Niedner v. Ortho-McNeil Pharm., Inc.*, 90 Mass. App. Ct. 306, 312 (2016), quoting *Everett v. Bucky Warren, Inc.*, 376 Mass. 280, 290 (1978). To sketch a design defect, a plaintiff must demonstrate "(1) the manufacturer's failure to exercise a reasonable degree of care under the circumstances; (2) proximate causation; and (3) injury and/or loss." *Geshke v. Crocs, Inc.*, 889 F. Supp.

[1] The FDA announced a Class II recall of the EGIAUXL stapler handle on February 18, 2016, stating that the "staplers fail to fire or partially fire" and that there were "reports of the instrument articulating level disengaging during use." FAC ¶ 38. The recall notice remained in effect until July 18, 2019, two months after Hunt's surgery. *Id.*; *see also id.* ¶ 55.

2d 253, 261 (D. Mass. 2012), citing *Ulwick v. DeChristopher*, 411 Mass. 401, 408 (1991).

A plaintiff has the further burden of establishing the availability of a technologically feasible and practical alternative design that would have reduced or prevented the harm she suffered. *Evans*, 465 Mass. at 428. However, the plaintiff need only convince a jury that the safer alternative design was feasible, "not that any manufacturer in the industry employed it or even contemplated it." *Haglund*, 446 Mass. at 748.

Hunt has adequately pleaded most of the elements of a design defect claim. From 2012 to 2017, Covidien "had submitted [to the FDA] more than 2,800 secret [adverse event] reports regarding 'malfunctions' related to" the stapler handle. FAC ¶ 55. In light of Covidien's knowledge of these incident reports, a jury could reasonably infer that at the time of Hunt's procedure, Covidien's design of the stapler handle was unreasonably dangerous and that Covidien failed to "exercise a reasonable degree of care under the circumstances." *Geshke*, 889 F. Supp. 2d at 261. Hunt has also pleaded sufficient facts that, taken as true, establish Covidien's defective design of the stapler handle as the proximate cause of her injuries, as the abscess would not have occurred but for the failure of the handle to properly seal the staple line. *See Doull v. Foster*, 487 Mass. 1, 16-17 (2021)

(Massachusetts uses a "but-for standard" in determining factual causation in negligence cases).

That said, Hunt has not adequately pleaded the existence of a reasonable alternative design to Covidien's stapler handle. Hunt in this regard alleges that "[t]he Covidien stapler components created a risk to the health and safety of patients that is far more significant and devastating than the risks posed by other products and procedures available to form a gastric sleeve with a secure staple line, and which far outweigh their utility." FAC ¶ 70. This is a conclusory statement that fails to identify what other product (or products), actual or feasible, could provide a safer alternative. *See Iqbal*, 556 U.S. at 678. The court will, however, grant leave for Hunt to amend the FAC for the limited purpose of pleading a reasonable alternative design. *See, e.g.*, *Ducat v. Ethicon, Inc.*, 534 F. Supp. 3d 152, 160 (D. Mass. 2021).

Failure to Warn (Count II)

Under Massachusetts law, "a manufacturer can be found liable to a user of the product if the user is injured [because of] the failure of the manufacturer to exercise reasonable care in warning potential users of hazards associated with use of the product." *Laaperi v. Sears, Roebuck & Co., Inc.*, 787 F.2d 726, 729 (1st Cir. 1986). As a defense, the manufacturer

may rely on the "learned intermediary" doctrine, which "provides that 'a . . . manufacturer's duty to warn of dangers associated with its product runs only to the physician; it is the physician's duty to warn the ultimate consumer.'" *Calisi v. Abbott Labs.*, 2013 WL 5441355, at *3 (D. Mass. Sept. 27, 2013), quoting *Cottam v. CVS Pharmacy*, 436 Mass. 316, 321 (2002).[2]

Courts use a burden-shifting framework "[t]o determine whether a plaintiff can make a prima facie case of negligence despite imposition of the learned intermediary rule." *Langlois v. Am. Med. Sys., Inc.*, 462 F. Supp. 3d 1, 3 (D. Mass. 2020). Under this framework, "the plaintiff carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known . . . ." *Garside*, 976 F.2d at 81.

Here, Hunt has carried her initial burden of demonstrating that Covidien failed to warn Hunt's physicians about the dangers and risks associated with the stapler handle. Specifically, Hunt alleges that Covidien utilized the FDA's Alternative Summary Reporting (ASR) program, which exempted certain complications from appearing on the FDA's public

[2] This doctrine is justified by the reasoning that "the prescribing physician, as the 'learned intermediary' standing between the manufacturer and the consumer/patient, is generally in the best position to evaluate the potential risks and benefits of [the product's use] and to advise the patient accordingly." *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992).

database, to withhold information about the nearly 2,800 adverse events relating to its stapler handle from 2012 to 2017. FAC ¶¶ 27-30. Thus, Hunt has plausibly demonstrated that Covidien did not exercise reasonable care in warning Hunt's surgeons about the potential hazards of using the stapler handle during the procedure. Further, Hunt has sufficiently alleged that Covidien's failure to adequately warn her physicians about the risks of using the stapler handle proximately caused her injury.

Count III – Negligence

"When warranty liability is alleged based on [a manufacturing or] design defect, it follows the same standard of proof as a negligence claim based on [manufacturing or] design defect." *Ducat*, 534 F. Supp. 3d at 160, citing *Haglund*, 446 Mass. at 747. Moreover, "[p]roof of the absence of a warning may, in a given products liability case, support simultaneous findings of negligence and breach of warranty." *Bavuso v. Caterpillar Indus., Inc.*, 408 Mass. 694, 699 n.8 (1990). As discussed above, Hunt has satisfied her burden at this stage to plead that Covidien was negligent in manufacturing the stapler handle and in failing to warn about the dangers associated with using the handle. And, as noted earlier, the court will grant leave for Hunt to amend the FAC to perfect her negligent design theory.

Count IV – Negligent Misrepresentation

To limn a negligent misrepresentation claim, a plaintiff must allege that the defendant,

> "(1) in the course of [its] business, or in a transaction in which [it] had a pecuniary interest, (2) supplied false information for the guidance of others (3) in their business transactions, (4) causing and resulting in pecuniary loss to those others (5) by their justifiable reliance on the information, and that [it] (6) failed to exercise reasonable care or competence in obtaining or communicating the information."

Elec. Ins. Co. v. Great S. Fin. Corp., 2016 WL 1452338, at *6 (D. Mass. Apr. 13, 2016), quoting *DeWolfe v. Hingham Centre, Ltd.*, 464 Mass. 795, 799-800 (2013); *see also Fox v. F & J Gattozzi Corp.*, 41 Mass. App. Ct. 581, 587 (1996), citing Restatement (Second) of Torts § 552(1) (1977).[3]

Here, as Covidien points out, Hunt fails to identify any specific statement or misrepresentation made by Covidien that Hunt's surgeons relied upon in using the allegedly defective stapler handle. Rather, Hunt only claims generally that Covidien misrepresented the safety of the staplers. FAC ¶¶ 86-87. The court agrees with Covidien that such a

[3] Although the FAC alleges personal injuries resulting from the misrepresentations attributed to Covidien, Massachusetts has not adopted Restatement (Second) of Torts § 311 (1965), which defines the tort of negligent misrepresentation to encompass *physical* injury. *See Gianocostas v. Interface Group-Mass., Inc.*, 450 Mass. 715, 727-728 (2008).

"naked," unsupported assertion is insufficient to state a claim of negligent misrepresentation, even at this early stage. *Twombly*, 550 U.S. at 557.

Count V –Massachusetts Consumer Protection Act (Chapter 93A)

Chapter 93A proscribes "[u]nfair methods of competition and unfair or deceptive acts and practice in the conduct of any trade or commerce . . . ." Mass. Gen. Laws ch. 93A, § 2(a). To state a claim for a violation, a plaintiff must plead "(1) a deceptive act or practice on the part of the defendant; (2) an injury or loss suffered by the plaintiff; and (3) a causal connection between the defendant's deceptive act or practice and the plaintiff's injury." *Wagner v. Fed. Home Loan Mortg. Corp.*, 2020 WL 5868299, at *4 (D. Mass. Oct. 2, 2020). Moreover, a Chapter 93A claim is actionable only if "the center of gravity of the circumstances that give rise to the claim is primarily and substantially within the Commonwealth." *Sonoran Scanners, Inc. v. PerkinElmer, Inc.*, 585 F.3d 535, 546 (1st Cir. 2009). The "heightened pleading requirement" of Fed. R. Civ. P. 9(b) also applies to Chapter 93A claims. *Munsell v. Colgate-Palmolive Co.*, 463 F. Supp. 3d 43, 52-53 (D. Mass. 2020); *see Int'l Floor Crafts, Inc. v. Adams*, 477 F. Supp. 2d 336, 341 (D. Mass. 2007) (claim "alleging fraud or mistake must provide particulars as to the time, place and content" of the fraudulent behavior).

The court concludes that Hunt has plausibly pleaded a cognizable Chapter 93A claim – namely, that Covidien intentionally obfuscated crucial safety information about the risks of the stapler handle on the FDA's nonpublic ASR program, thereby establishing a "but for" cause of Hunt's surgical injury. Although Covidien argues that the FAC does not contain any allegations of acts on its part that occurred in Massachusetts, the court agrees with Hunt that the "center of gravity" of Covidien's alleged actions is "primarily and substantially within the Commonwealth." *Sonoran Scanners, Inc.*, 585 F.3d at 546. Indeed, Covidien is headquartered in Massachusetts, and it operates and conducts its business – including its alleged obfuscation of safety information – in Massachusetts. FAC ¶¶ 2-6. Moreover, Hunt has stated with particularity the who (Covidien), where (Covidien's headquarters), when (2011 to 2019), and what (obfuscation of adverse events related to Covidien's stapler handle in the ASR program) sufficiently to surmount Rule 9(b)'s heightened pleading requirement. *See Alt. Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004).

ORDER

For the foregoing reasons, Covidien's motion to dismiss the FAC is DENIED as to Count I (insofar as it pleads a manufacturing defect), Count II, Count III (insofar as it pleads negligent manufacturing and negligent

failure to warn), and Count V. The court DISMISSES WITH PREJUDICE Count IV and DISMISSES WITHOUT PREJUDICE Counts I and III insofar as they plead design defect. Finally, the court GRANTS Hunt leave to amend the FAC for the limited purpose of pleading a reasonable alternative design for the stapler handle within 21 days from the issuance of this order.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE